UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,606	11/13/2006	Robert L. Fine	68074-A-PCT-US/JPW/CH	4899
23432 COOPER & DU	7590 09/30/200 J <b>NHAM.</b> LLP	8	EXAMINER	
1185 AVENUE	OF THE AMERICAS		YAO, LEI	
NEW YORK, NY 10036			ART UNIT	PAPER NUMBER
			1642	
			MAIL DATE	DELIVERY MODE
			09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
	10/587,606	FINE ET AL.					
Office Action Summary	Examiner	Art Unit					
	LEI YAO	1642					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 13 No.	ovember 2006.						
	action is non-final.						
<i>i</i> —	<del>/</del>						
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)⊠ Claim(s) <u>1-20,23,26,27.28,31,36 and 37</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) <u>1-20,23,26,27.28,31,36,37</u> are subject	8)⊠ Claim(s) <u>1-20,23,26,27.28,31,36,37</u> are subject to restriction and/or election requirement.						
Application Papers							
9)☐ The specification is objected to by the Examine							
10) The drawing(s) filed on is/are: a) acce		Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	te					

## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept **under PCT Rule 13.1**.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-20, 23, and 36, drawn to peptide comprising a first segment of SEQ ID NO: 1 linked to second segment having the sequence of SEQ ID NO:2 or a pharmaceutical composition comprising the peptide.

Group 2, claim(s) 26 and 28, drawn to a DNA, viral vector encoding the peptide of SEQ ID NO: 1 and 2

Group 3, claim(s) 31, drawn to an in vivo method of treating a subject suffering from cancer by administering to the subject the polypeptide.

Group 4, claim(s) 37, drawn to an in vitro method of inducing apoptosis of a cell that contains mutant p53 or over-expressed wild type p53 comprising the cell with the peptide of claim 1.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as group 1 and 2 do not related to s single general invention concept because the lack the same or corresponding special technical feature. The technical feature of group I are drawn to a polypeptide, which is shown by Vogelstein et al.,(US Patent 5527676) to lack novelty or inventive step. Vogelstein et al teach the amino acid sequence comprising the peptide of SEQ ID NO1 or SEQ ID NO: 2 that is a fragment of P53 as evidenced by sequence result (attached). Therefore, the invention Group II do not make

a contribution over the prior art. Because the antibody for calreticulin is known in the art, the technical feature of the Group II is not a special technical feature, the unity of invention (Group I- III) is lacking.

The additional method of group 4 does not correspond to the main invention, as they are neither a method of making, nor a method of using said composition.

Therefore, the group is not considered to share a special technical feature with the main invention within the meaning of PCT Rule 13.2, and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/587,606 Page 4

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./ Examiner, Art Unit 1642

/Larry R. Helms/ Supervisory Patent Examiner, Art Unit 1643